

REMARKS/ ARGUMENTS

Claims 1-26 are pending in this application.

Claims 1-26 were rejected under 35 U.S.C. §103(a) as being unpatentable over Wong et al. (U.S. Patent No. 5,534,263) in view of Conte et al. (U.S. Patent No. 5,780,057). This rejection is respectfully traversed.

According to MPEP §2141.02, “[a] prior art must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention.”

Claim 1 is an independent claim reciting:

[a]n active dosage form comprising: a first layer comprising an amount of swellable polymer, said amount being sufficient to swell said first layer such that the active agent dosage form is retained within a stomach of a subject; a second layer laminated with the first layer at a common surface, said second layer comprising a therapeutic amount of an active agent and being formulated to swell to a lesser extent than the first layer; and at least one band of insoluble material circumscribing only a portion of said first layer and said second layer, said at least one band of insoluble material binding together the first layer and the second layer.

The Wong et al. patent discloses active agent dosage forms. In Figure 6 of the Wong et al. patent (shown below), an active agent dosage form 80 has a first layer 82 and a second layer 84. The first layer 82 is formed from hydrophilic polymeric materials that erode over time upon exposure to a fluid environment of use. The second layer 84 is formed of a swellable material that disintegrates upon placement in the fluid environment of use. The second layer 84 is laminated with the first layer 82 at a common surface. Insoluble bands 86 and 88 are formed on the active agent dosage form, but the insoluble bands 86 and 88 circumscribe only portions of the first layer 82. This leads away from the claimed invention that recites “at least one band of insoluble material circumscribing only a portion of said first layer and said second layer, said at least one band of insoluble material binding together the first layer and the second layer.”

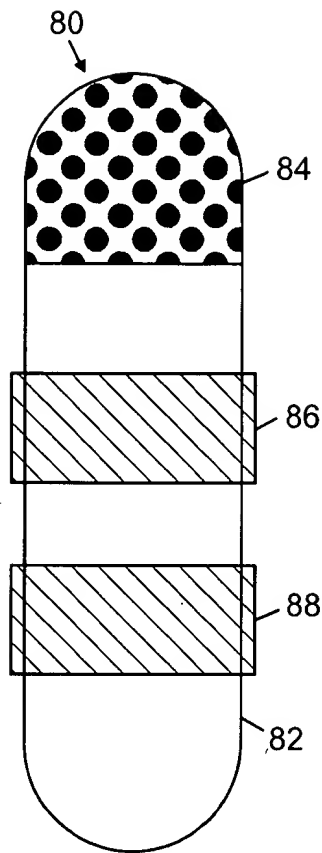


Figure 6 of the Wong et al. patent

The Wong et al. patent teaches providing at least two insoluble bands on a single layer of an active agent dosage form, where the insoluble bands provide controlled, prolonged release of the active agent from the matrix trapped between the bands. Nowhere does Wong et al. teach or disclose or suggest the desirability of forming the insoluble bands on the active agent dosage form so that they circumscribe the layers 82 and 84 and bind them together. In fact, binding the layers 82 and 84 together would change the principle of operation of the Wong et al. dosage form since Wong et al. relies on the layer 84 swelling and separating from the rest of the matrix to deliver an initial pulse of active agent (col. 8, line 66 to col. 9, line 1). In the claimed invention, an insoluble band is used to bind multiple layers together. Further, the insoluble band cooperates with the multiple layers to produce a geometrical shape in-situ that is surprisingly beneficial to achieving gastric retention and increased bioavailability.

The Conte et al. patent also discloses an active dosage form having a first layer and a second layer. The first layer consists of a swellable polymer and optionally a disintegrating

polymer and an active agent. The second layer contains the active agent to be administered and is made out of biodegradable and biocompatible polymeric materials. Conte et al. do not disclose or teach or suggest insoluble bands formed on the active agent dosage form. Therefore, the Conte et al. patent cannot overcome the deficiencies in the Wong et al. patent since it does not even contemplate usage of insoluble bands with an active agent dosage form.

From the foregoing, it is clear that claim 1 is not obvious over Wong et al. in view of Conte et al. Withdrawal of the rejection of claim 1 is respectfully requested. Claims 2-14 and 18-26, being dependent on claim 1, are likewise patentable in view of the foregoing arguments. Likewise, claims 15-17, which recite a method of treating a subject using the dosage form recited in claim 1, are patentable in view of the foregoing arguments.

Claims 1-26 were also rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,120,803 (the '803 patent) in view of Conte et al. and Wong et al. Applicants respectfully submit that this rejection is improper.

A judicially created doctrine of obviousness-type double patenting rejection is appropriate only where the claims of a second patent are not patentably distinct over the claims of a first patent which shares common ownership or inventorship.

Claims 1-12 of the '803 patent make no mention of a multilayer dosage form. Since claims 1-12 of the '803 patent make no mention of a multilayer dosage form, claims 1-12 cannot make obvious the following limitation in claims 1 and 15 of the instant application: "at least one band of insoluble material circumscribing only a portion of said first layer and said second layer, said at least one band of insoluble material binding together the first layer and the second layer." As previously discussed, this limitation is also not disclosed, taught, or suggested by the Wong et al. and Conte et al. patents. Therefore, claims 1-12 when combined with the Wong et al. and Conte et al. patents cannot make claims 1 and 15 obvious. For the same reasons, claims 2-14 and 16-26, being dependent on claims 1 or 15, are also not obvious. Withdrawal of the judicially created doctrine of obviousness-type double patenting rejection of claims 1-26 is respectfully requested.

The rejected claims have been amended and/or shown to be allowable over the prior art. Applicants believe that this paper is fully responsive to each and every ground of rejection cited by the Examiner in the Office Action dated August 13, 2003, and respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

Date: 2/12/2004

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